

(c) *Conditions of use.* (1) *Amount.* 4.54 to 5.45 grams per ton (5 to 6 parts per million) (1 to 1.2 pounds per ton).

(i) *Indications for use.* For prevention of coccidiosis caused by *Eimeria acervulina*, *E. tenella*, *E. brunetti*, *E. maxima*, *E. necatrix*, and *E. mivati*.

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter.

(2) [Reserved]

[54 FR 5229, Feb. 2, 1989, as amended at 54 FR 26732, June 26, 1989; 54 FR 32635, Aug. 9, 1989; 54 FR 33885, Aug. 17, 1989; 55 FR 23, Jan. 2, 1990; 55 FR 8460, Mar. 8, 1990; 55 FR 49616, Nov. 30, 1990; 59 FR 8134, Feb. 18, 1994; 61 FR 18082, Apr. 24, 1996; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001]

#### § 558.342 Melengestrol.

(a) *Specifications.* (1) Dry Type A medicated articles containing 100 or 200 milligrams (mg) melengestrol acetate per pound.

(2) Liquid Type A medicated article containing 500 mg melengestrol acetate per pound.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000009 for use of products described in paragraph (a) of this section.

(2) No. 021641 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.380 of this chapter.

(d) *Special considerations.* (1) Type B or C medicated feeds may be manufactured from melengestrol acetate liquid Type A articles or Type B or C medicated feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 per-

cent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable melengestrol acetate liquid Type B or C feed will not be subject to the requirements for mixing directions prescribed in paragraphs (c)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) Combination Type B or C medicated feeds containing lasalocid must be labeled in accordance with § 558.311(d)(5) of this chapter.

(4) Liquid combination Type B or C medicated feeds containing melengestrol acetate and lasalocid must be manufactured in accordance with § 558.311(d) of this chapter.

(5) Combination Type B or C medicated feeds containing monensin must be labeled in accordance with § 558.355(d) of this chapter.

(6) Liquid combination Type B or C medicated feeds containing melengestrol acetate and monensin must be manufactured in accordance with § 558.355(f)(3)(i) of this chapter.

(7) Liquid combination Type B or C medicated feeds containing melengestrol acetate and tylosin must be manufactured in accordance with § 558.625(c) of this chapter.

(8) Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement.

(e) *Conditions of use—(1) Cattle.*

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(i) 0.25 to 0.5 .....	.....	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)..	Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day..	000009, 021641

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(ii) 0.5 .....	.....	Heifers intended for breeding: For suppression of estrus (heat)..	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding..	000009, 021641
(iii) 0.25 to 0.5 ....	Lasalocid 100 to 360	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 30 grams (g) of lasalocid per ton; or add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to a ration of nonmedicated feed to provide 0.25 to 0.5 mg melengestrol acetate and 100 to 360 mg lasalocid/head/day. . Lasalocid provided by No. 046573 in § 510.600(c) of this chapter..	000009
(iv) 0.25 to 0.5 ....	Lasalocid 100 to 360 plus tylosin 90.	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses..	To administer 0.25 to 0.5 mg melengestrol acetate plus 100 to 360 mg lasalocid plus 90 mg tylosin/head/day:.. 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 10 to 30 g lasalocid and 8 to 10 g tylosin per ton; or. 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to 4.5 to 18 lb of a dry medicated feed containing 10 to 40 g tylosin per ton; or. 3. Add 0.5 to 2.0 lb/head/day of a dry pelleted medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article), 50 to 720 mg lasalocid, and 45 to 180 mg tylosin/lb to a ration of nonmedicated feed.. Lasalocid provided by No. 046573 and tylosin as tylosin phosphate by No. 000986 in § 510.600(c) of this chapter..	000009

## Food and Drug Administration, HHS

§ 558.342

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(v) 0.25 to 0.4 .....	Monensin 50 to 360	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section..	. Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 0.80 mg melengestrol acetate/lb to a feed containing 5 to 30 g monensin per ton; or add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 0.80 mg melengestrol acetate plus 25 to 720 mg monensin/lb to a nonmedicated feed to provide 0.25 to 0.40 mg melengestrol acetate and 50 to 360 mg monensin/head/day.. Monensin provided by No. 000986 in § 510.600(c) of this chapter..	000009
(vi) 0.25 to 0.4 ..	Monensin 50 to 360	Heifers fed in confinement for slaughter: As in item paragraph (e)(1)(i) of this section; and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ..	. Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 0.80 mg melengestrol acetate/lb to a feed containing 10 to 30 g monensin per ton; or add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 0.80 mg melengestrol acetate plus 25 to 720 mg monensin/lb to a nonmedicated feed to provide 0.25 to 0.40 mg melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight, up to 360 mg monensin/head/day.. Monensin provided by No. 000986 in § 510.600(c) of this chapter..	000009

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(vii) 0.25 to 0.5 ...	Monensin 50 to 360 plus tylosin 60 to 90.	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; for the prevention and control of coccidiosis due to <i>E. bovis</i> and <i>E. zuernii</i> ; and for reduced incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Actinomyces</i> ( <i>Corynebacterium</i> ) <i>pyogenes</i> ..	To administer 0.25 to 0.50 mg melengestrol acetate to 50 to 360 mg monensin plus 60 to 90 mg tylosin/head/day.. 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 5 to 30 g monensin and 8 to 10 g tylosin per ton; or. 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 25 to 720 mg monensin per pound to 4.5 to 18 lb of a dry medicated feed containing 10 to 40 g tylosin per ton; or. 3. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article), 25 to 600 mg monensin, and 45 to 180 mg tylosin/lb to a ration of nonmedicated feed.. Monensin and tylosin as tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter..	000009
(viii) 0.25 to 0.5 ..	Oxytetracycline 75 ...	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduction of liver condemnation due to liver abscesses..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb per pound to a feed containing 6 to 10 g oxytetracycline per ton; or add at the rate of 0.5 to 2.0 lb/head/day a dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 37.5 to 150 mg oxytetracycline/lb to provide 0.25 to 0.5 mg melengestrol acetate and 75 mg oxytetracycline/head/day.. Oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter..	000009

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(ix) 0.25 to 0.5 ....	Tylosin 60 to 90 .....	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses caused by <i>F. necrophorum</i> and <i>Actinomyces (Corynebacterium) pyogenes</i> ..	To administer 0.25 to 0.5 mg melengestrol acetate with 60 to 90 mg tylosin/head/day:.. 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 8 to 10 g tylosin per ton; or. 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 g tylosin per ton; or. 3. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article) plus 45 to 180 mg tylosin/lb to a ration of nonmedicated feed.. Tylosin as tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter..	000009

(2) Melengestrol may also be used with ractopamine alone or in combination as in § 558.500 of this chapter.

[42 FR 28535, June 3, 1977, as amended at 46 FR 18967, Mar. 27, 1981; 49 FR 39842, Oct. 11, 1984; 50 FR 1843, Jan. 14, 1985; 50 FR 16228, Apr. 25, 1985; 51 FR 7398, Mar. 3, 1986; 51 FR 36222, Oct. 9, 1986; 52 FR 2685, Jan. 26, 1987; 52 FR 33804, Sept. 8, 1987; 53 FR 27959, July 26, 1988; 55 FR 31828, Aug. 6, 1990; 57 FR 5053, Feb. 12, 1992; 59 FR 41241, Aug. 11, 1994; 60 FR 11028, Mar. 1, 1995; 62 FR 8373, Feb. 25, 1997; 62 FR 14304, Mar. 26, 1997; 63 FR 27845, May 21, 1998; 63 FR 41191, Aug. 3, 1998; 63 FR 66018, Dec. 1, 1998; 67 FR 47688, July 22, 2002; 69 FR 30198, May 27, 2004; 69 FR 51174, Aug. 18, 2004; 70 FR 2566, Jan. 14, 2005]

#### § 558.348 Mibolerone.

(a) *Approvals.* To No. 000009 in § 510.600(c) of this chapter for a canned dog food, each 6½ ounce can containing 30 or 60 micrograms of mibolerone.

(b) *Conditions of use*—(1) *Amount.* 30 micrograms for animals weighing up to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, or German Shepherds or German Shepherd mix weighing 30 to 80 pounds.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations.* Administer daily at least 30 days before expected initiation of heat and continue as long as desired, but for not more than 12 months. Mibolerone should not be used in bitches before first estrous period or in purebred Bedlington terriers. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 6617, Feb. 16, 1982]

#### § 558.355 Monensin.

(a) *Specifications.* Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the  $R_f$  value must be comparable to a reference standard (the  $R_f$  value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line), or, using High Performance Liquid Chromatography,